JUN 2 6 2001

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

Establishment:

- Address: Siemens Medical Systems, Inc.
  186 Wood Avenue South
  Iselin, NJ 08830
- Registration Number: 2240869
- Contact Person: Amy Shaw Hosler
  Senior Technical Specialist
  Telephone: (732) 321-4830,
  Telefax: (732) 321-4841

Device Name:

- Trade Name: *syngo* Multimodality Workstation
- Classification: Picture Archiving and Communications System (PACS)

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

- **Device Description and Intended Use:**
  This premarket notification covers Siemens new *syngo* Multimodality Workstation (MM-WS). *syngo* is a universal imaging platform based on Windows NT/2000. *syngo* offers a comprehensive software solution for medical imaging tasks and applications.

  The *syngo* MM-WS is a medical diagnostic workstation for real-time viewing, image manipulation, 3D visualization, communication and archiving of medical DICOM images. The *syngo* MM-WS can be used as a satellite console or a stand-alone review and post-processing workstation.

- **Technological Characteristics:**
  The *syngo* MM-WS described supports DICOM formatted images. The workstation is based on the Windows NT/2000 operating system.

- **General Safety and Effectiveness Concerns:**
  The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

- **Substantial Equivalence:**
  The *syngo* Multimodality Workstation, addressed in this premarket notification, are substantially equivalent to the following commercially available devices:

  Siemens Virtuoso Workstation – Real-time 3D workstation (K973010)
  GE Advantage Windows Workstation (960613)

  The *syngo* Multimodality Workstation described in this 510(k) has the same intended use and similar technical characteristics as the devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2001

Ms. Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K010938
Syngo Multimodality Workstation
Dated: March 28, 2001
Received: March 29, 2001
21 CFR §892.2050/Product Code: 90 LLZ

Dear Ms Rutherford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

INDICATIONS FOR USE

510(k) Number (if known): K010938
Device Name: *syngo* Multimodality Workstation (MM-WS)

Indications For Use:

The *syngo* Multimodality Workstation is a medical diagnostic workstation for real-time viewing, image manipulation, 3D-visualization, communication, and storage of medical images on exchange media, such as Computed Radiography (CR), Computed Tomography (CT), Digital X-ray (DX), IntraOral (IO), Magnetic Resonance (MR), Nuclear Medicine (NM), Positron Emission Tomography (PET), Radiation Therapy (RT), Ultrasound(US), X-ray Angiography (XA), X-ray Radiofluoroscopy (XRF), or Secondary Capture (SC) images. The workstation supports DICOM formatted images.

The MM-WS can be configured as a satellite console, sharing the database with the main console of a CT, MR, or radiographic/fluoroscopic imaging system, as well as stand-alone diagnostic review and post-processing workstation.

The MM-WS can be configured with a variety of *syngo*- or Windows NT/2000-based software options, which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques such as:

- Volume Rendering Technique (VRT)
- Multiplanar Reconstruction (MPR)
- Surface Shaded Display (SSD)
- Maximum/Minimum Intensity Projection (MIP)
- 3D Editor
- FlyThrough
- CT and MR Angiography (CTA and MRA)
- 3D Angiography reconstruction of X-ray images
- Quantitative Vascular Analysis (QVA)
- Image Fusion
- X-ray image composing (DR composing)
- Digital subtraction angiography (DSA)
- X-ray image intensity distortion correction
- CT bone mineral density (Osteo)
- CT Pulmo measurement
- CT dental display and measurement
- CT Calcium Scoring
- CT perfusion
- MR cardiac evaluation
- MR dynamic analysis
- MR mean curve
- MR bold evaluation
- MR perfusion
- MR spectroscopy
- Nuclear Medicine viewing and post-processing
- Virtual simulation of radiation planning
- Ultrasound read and display functions

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David G. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010938

Prescription Use ✓